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microgenics

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010496.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
phone: (510) 979-5150
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Contact: Sherrie Rinne
Regulatory Specialist

Summary Date: February 20, 2001

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): CEDIA® DAU Amphetamines / Ecstasy Assay

Name (usual): Amphetamines test system

Classification: 21 CFR 862.3100, Class II, DKZ (91)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

CEDIA DAU Amphetamines/Ecstasy Assay is substantially equivalent to CEDIA® DAU Amphetamines Assay (Microgenics Corporation, Fremont, CA), cleared under premarket notification K943993.

CEDIA DAU Amphetamines / Ecstasy Assay is identical or similar to its predicate in terms of: intended use, method principle, device components, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

CEDIA DAU Amphetamines / Ecstasy Assay is a two-reagent set intended to be used with automated clinical chemistry analyzers. The assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme ß -galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED) spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, to generate a color change that can be measured spectrophotometrically.

In the CEDIA DAU Amphetamines / Ecstasy Assay, drug in the sample competes with drug conjugated to ED for antibody binding sites. If drug is present in the sample, it binds to antibody, leaving the ED–drug conjugate free to reassociate with EA to form active ß-galactosidase. If no drug is present in the sample, antibody binds to the ED–Amphetamies - Ecstasy conjugate, inhibiting the reassociation of inactive ß-galactosidase fragments, and thus reducing the amount of active enzyme formed. The amount of active enzyme formed, and resulting absorbance change, are proportional to the amount of Amphetamines / Ecstasy present in the sample. A concentration of Amphetamines / Ecstasy ≥ either 500 ng/ml or 1000 ng/mL (depending on the cutoff used) in urine is considered a positive indicator of Amphetamines or Ecstasy abuse.

Intended Use (21 CFR 807.92 (a)(5))

The CEDIA DAU Amphetamines / Ecstasy Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative assay of amphetamines in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of amphetamines use or overdose. For use in clinical laboratories only.

CEDIA Amphetamines/Ecstasy is uniquely designed to recognize samples that contain any of the Ecstasy Drugs, a group of ring substituted methylenedioxy analogues of amphetamine including 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxymethamphetamine (MDMA) and 3,4-methylenedioxyethylamphetamine (MDEA).

This assay is intended for use on automated clinical analyzers. The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromotography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The CEDIA Amphetamines/Ecstasy ass provides a choice of two cutoff levels: 500 and 1000 ng/mL. The assay is appropriate for testing under the Substance Abuse and Mental health Services Administration (SAMHSA, formerly NIDA) guidelines, which currently recommend a cutoff of 1000 ng/mL

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between CEDIA DAU Amphetamines / Ecstasy Assay and the predicate device follows.

Comparison Table:

CEDIA® DAU Amphetamines / Ecstasy Assay and CEDIA® DAU Amphetamines Assay

Device Name	CEDIA® DAU Amphetamines Assay (K043095)	CEDIA® DAU Amphetamines / Ecstasy Assay (new device)
Indications for Use	The CEDIA DAU Amphetamines Assay is a homogeneous enzyme immunoassay for the qualitative and semiquantitative assay of Amphetamines in human urine. Measurements are used in the diagnosis and treatment of amphetamines use or overdose.	The CEDIA DAU Amphetamines / Ecstasy Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative assay of amphetamines in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of amphetamines use or overdose. For use in clinical laboratories only. CEDIA Amphetamines/Ecstasy is uniquely designed to recognize samples that contain any of the Ecstasy Drugs, a group of ring substituted methylenedioxy analogues of amphetamine including 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxymethamphetamine (MDMA) and 3,4-methylenedioxyethylamphetamine (MDEA). This assay is intended for use on automated clinical analyzers. The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromotography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used. The CEDIA Amphetamines/Ecstasy ass provides a choice of two cutoff levels:500 and 1000 ng/mL The assay is appropriate for testing under the Substance Abuse and Mental health Services Administration (SAMHSA, formerly NIDA) guidelines, which currently recommend a cutoff of 1000 ng/mL

Device Name	CEDIA DAU Amphetamine Assay (K040966)	CEDIA DAU Amphetamines / Ecstasy Assay (new device)
Method Principle	The assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. It is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.	The assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. It is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.
Components	- Enzyme Acceptor Reagent - Enzyme Acceptor Buffer - Enzyme Donor Reagent - Enzyme Donor Buffer	- Enzyme Acceptor Reagent - Enzyme Acceptor Buffer - Enzyme Donor Reagent - Enzyme Donor Buffer
Risk to patient	In vitro device, positive results must be confirmed by GC/MS, or other method	In vitro device, positive results must be confirmed by GC/MS, or other method
Clinical Performance	Accuracy: Accuracy against a reference method was 97% (199 true positives, 94 true negatives); Total Imprecision: Percent CVs across 4 levels of Amphetamines concentrations were between 3% and 4%.	Accuracy: Accuracy against a reference method was ≥92% (159 to 164 true positives, 25 true negatives, ≥12 close to the cutoff value); Total Imprecision: Percent CVs across 6 levels of Amphetamines / Ecstasy concentrations were between 6% and 9%.

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))

The CEDIA DAU Amphetamines / Ecstasy Assay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, linearity, accuracy, and specificity.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as rate %CVs for both inter-assay and intra-assay testing were below 2%.

The CEDIA DAU Amphetamines / Ecstasy Assay is linear between 375 and 625 ng/mL or 750 and 1250 ng/mL for the 500 and 1000 ng/mL cut-offs respectively. The assay also shows good separation in the decision-making ranges of between 375 and 625 ng/mL or 750 and 1250 ng/mL for the 500 and 1000 ng/mL cut-offs respectively.

Accuracy studies showed good performance of the CEDIA DAU Amphetamines / Ecstasy Assay as compared to the GC/MS reference method when a comparable cut-off is used. Accuracy studies showed good performance of the CEDIA DAU Amphetamines / Ecstasy Assay as compared to the GC/MS reference method. The clinical sensitivity of the assay was 94 to 99%, indicating that percentage of positive samples were correctly identified. Specificity ranged from

64 to 68%, when the 500 ng/mL assay was compared to the 500 ng/mL GC/MS cut-off and was 81% when the 1000 ng/mL cut-off was compared to the 500 ng/mL GC/MS cut-off indicating those percentages of Amphetamines / Ecstasy-negative samples were correctly identified.

Specificity testing demonstrated that the CEDIA DAU Amphetamines / Ecstasy Assay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds other than amphetamines and the ecstasy compounds.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The CEDIA DAU Amphetamines / Ecstasy Assay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 9 2001

Ms. Sherrie Rinne
Regulatory Specialist
Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538

Re: 510(k) Number: K010496
Trade/Device Name: CEDIA® DAU Amphetamines/Ecstasy Assay
Regulation Number: 862.3610
Regulatory Class: II
Product Code: LAF
Dated: May 9, 2001
Received: May 11, 2001

Dear Ms. Rinne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K010496

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010496

Device Name: CEDIA® DAU Amphetamines / Ecstasy Assay

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)